REMARKS

Claims 1-25 are pending in the present application. Of these, claims 7-19 and 21-23 remain withdrawn from consideration. No amendments are being introduced herein and thus, this paper introduces no new matter. Upon entry of the present paper, claims 1-6, 20, 24, and 25 will remain pending and under examination. Applicants believe these claims are in condition for allowance.

The December 22, 2009 Office Action

Office Action's Claim Rejections under 35 U.S.C. § 102

Claims 1-3, 20, 24 and 25 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Pfirrmann (U.S. 4,587,268). According to the Office Action, Pfirrmann teaches a composition comprising a resorbable aqueous gel having dissolved or dispersed therein one or more water-soluble medicament such as an antibacterial compound. The Office Action stated that Pfirrmann further teaches the use of such composition for healing an infection of bone or other tissue, and directed attention to the abstract; to column 1, lines 55-68; and to column 3, lines 17-23. The Office Action stated that resorbable gel includes fibrous protein, collagen, and gelatin (column 2, lines 1-28) and that antibacterial compound includes methylol transfer agents such as taurolidine or taurultam (column 3, lines 25 through column 4, lines 1-1 1). According to the Office Action, Pfirrmann also teaches the amount of taurolidine is from 0.5% to 5% by weight (column 4, lines 12-46).

The Office Action acknowledged that Pfirrmann does not explicitly teach that the system is also useful for preventing or inhibiting growth of cancer cells. However, in the opinion expressed in the Office Action, such limitation is inherent because, according to the Office Action, Pfirrmann teaches the use of the same antineoplastic agent in the claimed concentration. The Office Action stated that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. The Office Action further stated that products of identical chemical composition cannot have mutually exclusive properties and that a chemical composition and its properties are inseparable. The Office Action concluded, therefore, that if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

In response, Applicants respectfully traverse the rejection. Applicants' claimed invention is directed to, *inter alia*, an antineoplastic composition comprising an antineoplastic-effective amount of a methylol transfer agent (MTA) in combination with a biodegradable adhesive capable of adhering to tissue of a living subject. Pfirrmann (4,587,268) does not disclose such a composition. Specifically, the '268 patent does not disclose the adherence aspect of the present application. The '268 patent refers to an aqueous gel formed from cross-linked fibrous proteins (column 1, lines 59-60). The gel is preferably in the form of a shaped solid such as a rod or in the form of a granulate (column 2, lines 7-11). The '268 patent continually suggests ways to make the gelatin more solid and therefore less likely to adhere. For example, adding calcium phosphate (column 3, lines 9-10), leaving the gel out to dry for longer periods of time (column 5, lines 59-64), and drying the gel in an oven to increase the firmness and granulability (column 6,

lines 20-21). It is also necessary to cross-link the gel in the '268 patent to ensure the cohesion of the gel, making it a solid (column 4, lines 31-32). The '268 patent never discloses or suggests the gel as an adhesive. Rather, the teaching suggests the gel should be in the form of a rod, which does not suggest adherence, or in the form of a granulate, which teaches *away* from adherence. That is, the more granulate the gel is, the less likely it will adhere. For at least these reasons, the '268 patent cannot anticipate the present claims and thus, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

Office Action's Claim Rejections Under 35 U.S.C. § 103

Claims 1-6, 20, 24 and 25 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Alt et al. (U.S. Pat. 5,788,979) in view of Lehner (U.S. Pat. 6,258,797). According to the Office Action, Alt teaches a biodegradable carrier composition comprising active agent, and biodegradable and adhesive polymers such as gelatin and the like (column 3, lines 30-67; and column 4, lines 1-29). The Office Action stated that Active agent includes an antibiotic (column 7, line 22).

The Office Action acknowledged that Alt does not expressly teach the claimed "antibiotic" agent.

It is important to note that taurolidine and taurultam are not antibiotics, although they are potent antimicrobial agents.

According to the Office Action, Lehner teaches an anti-infection sealing composition comprising 0.5-3% taurolidine or 1-7.5% taurultam (abstract; and column 4, lines 6-21). In the opinion expressed in the Office Action, it would have been obvious to one of ordinary skill in the

art to optimize the biodegradable carrier composition of Alt to include taurolidine or taurultam as an "antibiotic" agent to obtain the claimed invention (though, as noted above, they are not antibiotics). This, the Office Action stated, is because Alt teaches the desirability for obtaining a composition suitable for coating medical devices, because Alt teaches that it is well known and desirable to incorporate an "antibiotic" agent in a biodegradable coating composition. The Office Action stated that this also is because Lehner teaches the use of an "antibiotic" agent such as taurolidine or taurultam in a composition for sealing medical devices (column 3, lines 25-31; and column 4, lines 6-10), because Lehner teaches that antibacterial compounds such as taurolidine and taurultam are the only compounds which until now have worked satisfactorily (column 3, lines 33-38), and because Lehner teaches that taurolidine or taurultam has not been found to give rise to any adverse side reaction (column 4, lines 47-49).

In response, Applicants respectfully traverse the rejection. Applicants' claimed invention is directed to, *inter alia*, an antineoplastic composition comprising an antineoplastic-effective amount of a methylol transfer agent (MTA) in combination with a biodegradable adhesive capable of adhering to tissue of a living subject. As the Office Action acknowledged, Alt does not teach or suggest the use of a methylol transfer agent and, consequently, cannot teach an antineoplastic-effective amount of such an agent. More significantly, Alt does not disclose the adherence aspect of the present application. In fact, nearly the entire disclosure of Alt is dedicated to describing a way to avoid adherence to tissue.

Alt refers to liquid coating materials for application to the surface of biologically compatible materials and devices. The device most prominently discussed is a coated stent for insertion into a vessel. The purpose of Alt's coating, which is typically an anticoagulant coating,

is to inhibit tissues, generally blood components, from adhering to the surface of the device. The coating itself is lightly adhered to the surface of the device (see col. 4, lines 1-2), but as stated at column 3, lines 19-46, a principal goal of the invention is to prevent the deposition of thrombi and coagulation deposits on the material, noting that blood components "are unable to adhere to the biomaterial surface" because of a continuous cleansing action provided by the coating. It is further stated at column 4, lines 45-61, that "[a]nti-adhesive peptides . . . are also effective as coating material" and that "[t]he slow release of thrombocytic aggregation or thrombocyte receptor antagonists additionally prevent adhesion and aggregation." Col. 7, lines 5-7 note that contact with the blood or tissue causes "undesirable effects" which are "sought to be prevented by the coating." Finally, column 10, lines 60-65 state that "the biodegradable coating of the present invention provides several beneficial results or functions, including . . . a continual removal of anything which is atop the outer surface of the coating to prevent adherence to it."

Accordingly, it is clear that the Alt reference is directed to a coating on a biomaterial which is designed to prevent adherence of tissue to it, precisely the opposite function of the presently claimed invention, and thus, Alt strongly teaches away from the present invention.

Lehner does not cure the deficiencies of Alt. First, Lehner does not teach or suggest the adherence aspect of the invention in any way. In fact, like Alt, Lehner suggests at column 4, lines 51-53, that the use of taurultam and taurolidine in accordance with the invention described therein "appears to have the further advantage that it can reduce the adhesiveness of fibrin deposits within a plastic delivery system." For this reason alone, a combination of Alt and Lehner cannot render the present claims obvious.

Furthermore, Lehner, in fact makes no mention of a neoplastic composition or even that the taurultam or taurolidine solutions referred to therein (as antimicrobials), are useful in any manner as *a component* of a neoplastic, or other composition. What Lehner teaches is a method for combating infections or sepsis, by sealing or flushing a liquid delivery system (e.g., a catheter or port system) with an antimicrobial solution of taurultam or taurolidine *when the system is not in use*. This is stated clearly at column 3, lines 32-37:

> We have now found that substantial advantages in the prevention and/or treatment of infection under these circumstances can be obtained if the delivery system is filled, flushed out or sealed when not in use with solutions containing the antibacterial compounds taurultam or taurolidine. These are the only compounds which until now have worked satisfactorily.

This is illustrated at columns 4-5, which describe a typical procedure according to the invention. Specifically, a chamber of a port delivery system is injected with a taurolidine solution and sealed up until chemotherapeutic administration is due. Prior to introducing the chemotherapeutic agent, the taurolidine solution is rinsed into the bloodstream using saline. The chemotherapeutic agent is then injected into the chamber to be taken into the body over time. This method has no similarity to the presently claimed invention.

It also is difficult to envision how the teachings of Lehner could in fact be combinable with those of Alt, as the principles of operation of each also are not similar. However, even if one were to attempt some combination of the teachings in the two references, there simply is no way to arrive at Applicants' claimed invention. Accordingly, for at least the reasons provided, the present claims are not rendered obvious by the art of record. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

Applicants believe all of the objections and rejections set forth in the December 22, 2009 Office Action have been overcome and the application is in condition for allowance. The Office is invited to telephone the undersigned if it is deemed to expedite prosecution.

Respectfully submitted,

By _____

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